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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,382	10/03/2001	Su-Chun Zhang	960296.98211	9657

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EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 07/01/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/970,382	ZHANG ET AL.
Period for Reply	Examiner	Art Unit
	Quang Nguyen, Ph.D.	1636
<p>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</p>		
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<p><b>Status</b></p> <p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>18 April 2003</u>.</p> <p>2a)<input type="checkbox"/> This action is <b>FINAL</b>.                            2b)<input checked="" type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>		
<p><b>Disposition of Claims</b></p> <p>4)<input checked="" type="checkbox"/> Claim(s) <u>1,3-11 and 13-17</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input checked="" type="checkbox"/> Claim(s) <u>1 and 5-11</u> is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>3,4 and 13-17</u> is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.</p>		
<p><b>Application Papers</b></p> <p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.</p> <p>If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<p><b>Priority under 35 U.S.C. §§ 119 and 120</b></p> <p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All    b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <p>1.<input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p>2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p>3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<p><b>Attachment(s)</b></p> <p>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10,11,15</u>.</p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____.</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____</p>		

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 18/2003 has been entered.

Amended claims 1, 3-11 and 13-17 are pending in the present application, and they are examined on the merits herein.

### ***Response to Amendment***

The Declaration filed on April 18/2003 as Paper No. 14 under 37 CFR 1.131 is sufficient to overcome the Carpenter (WO 01/88104) reference.

### ***Claim Objections***

Claim 14 is objected to because of the following informality: the phrase "wherein the cells are form rosette formations" is grammatically incorrect. Appropriate correction is required.

***Following is a new ground of rejection.***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, the phrase "wherein the treatment leads to the preferential detachment of rosette formations and the preferential attachment of surrounding cells that are not in a rosette formation" is unclear. This is because does enzymatic treatment really confer preferential attachment to a certain cell population? Enzymatic treatment is usually employed to detach cells. Examiner suggests the phrase - - wherein the treatment leads to the preferential detachment of cells in rosette formations relative to surrounding cells that are not in a rosette formation - - can obviate this rejection.

Claims 4 and 13 recite the limitation "step (d)" in line 2 and line 1 of the claims respectively. There is insufficient antecedent basis for this limitation in the claim. This is because there is no step (d) in the main claim 1 from which both claims 4 and 13 are dependent upon. The metes and bounds of the claims are not clearly determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Brustle et al.

(PNAS 94:14809-14814, 1997).

The claim is drawn to an isolated cell population comprising at least 72% neural precursor cells wherein the cells are capable of forming rosette formations.

Brustle et al. disclose the preparation of a population of cells wherein the majority of the cells acquire an elongated phenotype strongly reminiscent to neuroepithelial precursor cells, and that these cells express nestin, an intermediate filament typically present in neural precursor cells (page 14810, col. 1, first paragraph of the Result section). After 6 days in culture, typically more than 80% of the cells were nestin-positive. Additionally, Brustle et al. teach that upon transplantation of these cells into embryonic rat brain, they form large clusters containing neuroepithelial formations (e.g. tightly packed neural tubes consisted of columnar epithelium with high mitotic activity at the luminal surface (rosette formations) as well as the cells can differentiate into neurons, astrocytes and oligodendrocytes (page 14811, col. 1, second paragraph).

Accordingly, the neuroepithelial precursor cells population of Brustle et al. meets every limitation of the instant claim. Therefore, Brustle et al. anticipate the instant claim.

Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawata et al. (Cancer Research 51:2655-2669, 1991).

Kawata et al. disclose the preparation of a newly isolated human cell clone PA-1/NR that stably produces neural rosette structures in cells in monolayer or within *in vitro* multicellular spheroids (page 2657, col. 2, fourth paragraph). The PA-1/NR cells in monolayer expressed neuroectoderm-associated antigens HNK-1, NC-1 and A2B5 and since the cells in monolayer are derived from the same clone, neural rosette forming cells of Kawata et al. are indistinguishable from the isolated cell population of the present invention.

Therefore, Kawata et al. anticipate the instant claims.

Claims 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (WO 01/83715; IDS).

Lee et al. disclose the preparation and expansion of nestin-positive CNS precursor cells (cell population at stage 4) generated from undifferentiated ES cells (see pages 20-23 and abstract). The precursor cells have been expanded in a minimal essential media that can be supplemented with only b-FGF (5 ng/ml to 30 ng/ml). Since the nestin-positive CNS precursor cells population of Lee et al. were generated from the same ES cells via the production of embryoid bodies that are cultured in the same culture media, the CNS precursor cells would inherently possess the ability to form rosette formations.

Accordingly, Lee et al. anticipate the instant claims.

***Conclusions***

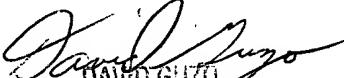
***Claims 1 and 5-11 are allowed..***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (703) 308-1906, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.**

*Quang Nguyen, Ph.D.*

  
DAVID GUZO  
PRIMARY EXAMINER